Suvorexant Advisory Committee Meeting Briefing Document

Addendum

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

May 22, 2013

Merck Sharp & Dohme Corporation

Whitehouse Station, New Jersey, U.S.A.

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Sponsor's Revision of Suvorexant Dosing Recommendation

Merck's original dosing recommendation, as stated in the Background Document, was to initiate therapy with 40 mg (30 mg in elderly) with a reduction to 20 mg (15 mg in elderly) for patients based on individual tolerability. This recommendation was based on the design of the Phase 3 program and the pre-specified statistical analysis plan (that first evaluated the 40/30 mg dose before evaluation of the 20/15 mg dose).

Upon further consideration of evolving dosing practices in the field, input from external consultants and the recent labeling change for zolpidem dosing, released after Merck prepared its Background Package, Merck has revised our dosing recommendations to the following:

> Use the lowest effective dose for the patient. The usual starting dose should be 20 mg (15 mg in elderly). For patients whose symptoms persist and who demonstrate acceptable tolerability, a dose increase to 40 mg (30 mg in elderly) may be considered.